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(54) Title: SHELLAC ENCAPSULANT FOR ACTIVE INGREDIENTS IN CHEWING GUM

(57) Abstract

A food-grade shellac is used as an encapsulating agent for active ingredients in chewing gum compositions. The shellac provides an impermeable, hydrophobic coating which is substantially insoluble in the chewing gum base.

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SHELLAC ENCAPSULANT FOR ACTIVE INGREDIENTS IN CHEWING GUM

This invention relates in general to chewing gum compositions and, in particular, to the improvement comprising a food-grade shellac encapsulant for active chewing gum ingredients.

As is well-known in the art, chewing gum comprises a neutral and tasteless masticatory chewing gum base and one or more non-masticatory active ingredients mixed into the base. As used herein, an "active ingredient" is an ingredient such as a sweetener, a flavoring agent or a food-grade acid which determines flavor and taste characteristics of the gum; a body-treating ingredient such as a medicinal drug or pharmaceutical agent which is released at a gradual rate and ingested during chewing; or a breath-freshening ingredient which treats or reduces oral malodor. In addition, the chewing gum may, and usually does, contain water-soluble and usually sweet non-masticatory bulking agents, a coloring agent and a plasticizing agent, the latter employed to improve the texture of the gum.

Certain active chewing gum ingredients benefit from or require encapsulation in order to achieve a gradual and controlled release of the ingredients during chewing or to promote their stability in chewing gum. For example, certain artificial sweeteners such as the dipeptide sweetener aspartame (L-aspartyl-L-phenylalanine methyl ester) have been found to be excellent sugar substitutes in chewing gum. However, the stability of artificial dipeptide sweeteners is a function of water activity, time, temperature and pH. Under unfavorable

conditions, aspartame spontaneously converts to diketopiperazine with proportional loss of sweetness. Aspartame also degrades as the result of reactions with aldehydes present in certain flavors. In order to maintain the stability and sweetness of aspartame in chewing gum, it is necessary to reduce as far as possible the exposure of the aspartame to moisture, certain flavors and certain pH conditions.

Although the general technique of encapsulating ingredients is well-known, the prior art known to applicant does not teach satisfactory encapsulating agents for active chewing gum ingredients. For example, U. S. Patent Nos. 4,122,195 and 4,139,639 disclose encapsulation of aspartame in Capsul dextrin and gum arabic. However, such encapsulants, which are hydrophilic and moisture-permeable, have been found to be of only limited effectiveness in preventing the degradation of aspartame in chewing gum.

While it would seem that hydrophobic encapsulating agents would provide better impermeability and gradual release characteristics than hydrophilic coatings, applicant is unaware of any hydrophobic coatings which have been successfully employed in the past for active chewing gum ingredients. Most hydrophobic materials which could be used as encapsulants, such as polyvinyl acetate, waxes and fats, are dissolved in the chewing gum base when they are mixed into the heated gum mass during the gum manufacturing process. Other hydrophobic materials such as high molecular weight polyvinyl acetate and styrene butadiene rubber are substantially insoluble in the food-grade solvents which are required in encapsulating processes. Applicant is unaware of any prior disclosure of encapsulating materials which have both of the necessary qualities of being insoluble in chewing gum base yet sufficiently soluble in the food-grade solvents used in encapsulating processes.

According to the present invention there is provided a chewing gum composition comprising gum base, a food-grade shellac encapsulant for one or more active ingredients of the group consisting of a sweetener, a flavoring agent, a food-grade acid, a pharmaceutical agent and a breath-freshening agent.

The shellac encapsulant, which is hydrophobic and insoluble in the gum base yet soluble in food-grade solvents such as ethanol, provides a substantially impermeable coating for such active gum ingredients and achieves a controlled, gradual release of the ingredients as the encapsulant is broken down during chewing.

Another advantage is that the shellac coating prevents flavors and other hydrophobic ingredients from becoming irreversibly absorbed by the gum base, thereby permitting use of a smaller quantity of the ingredient to achieve its desired effect.

When used to coat dipeptide sweeteners, the shellac encapsulant substantially maintains their sweetness during storage of the chewing gum by minimizing the degradation of the dipeptide sweeteners to diketopiperazine or their reaction with aldehydes in certain chewing gum flavors.

In the present invention, the chewing gum comprises any chewable and substantially water-insoluble gum base in an amount ranging from approximately 18% to 99%, but perferably about 25%, by weight of the total chewing gum composition. The gum base may contain a calcium carbonate filler instead of a talc filler even if the chewing gum composition comprises the dipeptide sweetener aspartame (L-aspartyl-L-phenylalanine methyl ester, originally disclosed in U. S. Patent Nos. 3,492,131 and 3,642,491) or food acidulants. Although the calcium carbonate base has better chewing characteristics and is less expensive than the talc base, prior to the present invention, a talc base was in some cases preferred for

use with aspartame and acids because calcium carbonate raises the gum pH and promotes degradation of the aspartame and neutralization of the acids; see, for example, U. S. Patent No. 4,246,286 which covers gum products which are substantially free of calcium carbonate and strongly basic constituents in order to provide a storage-stable aspartame chewing gum.

The chewing gum comprises one or more active ingredients in the group consisting of sweeteners, flavoring agents, food-grade acids, pharmaceutical agents or breath-freshening agents, with at least one of the active ingredients encapsulated in a food-grade shellac. The shellac encapsulation preferably is accomplished using a known fluidized bed coating method or a known roller bed coating method, although other coating methods can be used.

In the fluidized bed coating method, particles of the active ingredient are suspended in a stream of pressurized air and sprayed with a solution of the encapsulating agent. When the ethanol solvent for the shellac evaporates, a coated ingredient particle remains. The velocity of the air flow can be adjusted so that when the desired coating level is reached, the weight of the coated particle causes it to drop out of the air stream and into a collecting bin.

In the roller bed coating method, particles of the active ingredient are suspended in a solution of the encapsulating agent and its solvent. The active ingredient is not appreciably soluble in the solvent. The suspension is deposited on a heated, rotating drum; the heat evaporates the solvent, leaving coated ingredient particles which are scraped from the roller. This method can be repeated in order to obtain thicker coatings, but different solvent systems or more rapid roller speeds must then be used to avoid re-dissolving of the encapsulant.

The shellac encapsulant provides a moisture-impermeable hydrophobic coating which is not soluble in the chewing gum base, thereby affording excellent protection for the active gum ingredients, particularly dipeptide sweeteners which are sensitive to certain moisture and pH conditions and aldehydes which may be present in the gum. At the same time, the shellac encapsulant effects controlled, gradual release of the active ingredients to achieve extended gum sweetness and flavor and sustained dispensation of pharmaceutical agents.

The sweetener in the chewing gum may comprise a high-potency sweetener, that is, one having a sweetness greater than about twenty times that of sucrose. Such a sweetener may be aspartame, saccharin, cyclamate, thaumatin, acesulfame K, dihydrochalcones, or combinations thereof. A preferred sweetener is aspartame present in an amount ranging from about 0.025% to about 2.0% by weight of the gum composition. For this artificial sweetener, the shellac encapsulating agent is present in an amount ranging from about 5.0% to about 90.0%, but perferably about 25.0%, by weight of the aspartame.

The chewing gum composition may comprise flavoring agents, preferably spray or freeze dried flavoring agents such as essential oils and artificial flavors in an amount determined by preference; but generally the active flavoring agents comprise about 1% by weight of the chewing gum composition. Shellac encapsulation extends the release of the flavors and protects certain flavors from oxidation and other breakdown reactions. The shellac coating also prevents the absorption of flavor into the gum base, thus reducing the amount of costly flavor needed for a desired flavor level.

With some flavors, most notably fruit flavors, it is desirable to use a food-grade acid to impart a tartness to the gum. For this purpose, acids such as

malic and citric acids can be employed at a level determined by preference, generally about 1% of the total gum weight. Shellac encapsulation of such acids results in their slow release during chewing to achieve a moderate, extended tartness. Other acids such as lactic and tartaric, which in the past were sometimes avoided due to their high solubilities and resulting undesirable tartness, can be used beneficially when encapsulated with shellac. The encapsulation also prevents neutralization of these acids when exposed to alkaline substances such as calcium carbonate.

Chewing gum has been used as a vehicle for pharmaceutical or medicinal agents such as aspirin and silver acetate, the latter employed as a smoking deterrent. Pharmaceutical agents are incorporated into the gum mass to delay and control the rate at which the pharmaceutical is released upon chewing of the gum for safe and effective dispensation. According to the present invention, shellac encapsulation of such pharmaceutical agents further controls their release rate and prevents irreversable absorption of such agents by the gum base.

The chewing gum composition may also comprise a breath-freshening agent which treats or reduces oral malodor. A suitable breath-freshening ingredient is copper gluconate (see, for example, U. S. Patent No. 2,894,876) but other salts of copper or zinc may be used.

The chewing gum optionally comprises a coloring agent in a conventional amount of about 0.1% to about 2.0% by weight and a plasticizing agent in an amount of about 0.1% to about 25% by weight of the gum composition. Liquid flavors, which are not encapsulated, may also be included in the gum.

The chewing gum may also comprise a sweet, water-soluble bulking agent although non-caloric or low-calorie gums can be prepared using no bulking agents or bulking agents which have little or no assimilable caloric

value. For sugar gums, the bulking agent may consist of dextrose, sucrose, maltose, dextrin, dried invert sugar, fructose, levulose, galactose, corn syrup or corn syrup solids, or combinations thereof. For sugarless gums, the bulking agent may comprise Polydextrose (a low-calorie carbohydrate manufactured by Pfizer) or a sugar alcohol such as sorbitol, mannitol, xylitol, or combinations thereof. Such bulking agents are present in an amount ranging from about 30% to about 80% by weight of the entire chewing gum composition.

The chewing gum can be manufactured in a conventional manner. First, the base is heated and placed in a mixer. If coloring is desired, it may be added at this point, followed by the bulking agent, if any, the shellac-encapsulated active ingredient or ingredients and the plasticizing agent. When the chewing gum is removed from the mixer, the mixture is rolled or extruded, cut into individual pieces, cooled and then wrapped in a known manner.

EXAMPLE I

A sugarless chewing gum containing shellac-encapsulated aspartame was made according to the following formulation:

Ingredient	Percent By Weight
Gum Base	27.00
Sorbitol Powder	41.525
70% Sorbitol Solution	10.00
Mannitol Powder	12.00
Peppermint Flavor	1.20
Glycerine	8.00
Color	0.025
Shellac-encapsulated Aspartame	0.25

EXAMPLE II

A sugar chewing gum containing shellac-encapsulated aspartame can be made according to the following formulation:

Ingredient	Percent By Weight
Gum Base	20.00
Corn Syrup	13.00
Sugar	64.75
Glycerine	1.00
Peppermint Flavor	1.00
Shellac-encapsulated Aspartame	0.25

For a breath-freshening gum, 0.006% by weight of shellac-encapsulated copper gluconate is added to the gum illustrated in Example II.

EXAMPLE III

A chewing gum containing a shellac-encapsulated food-grade acid and shellac-encapsulated aspartame can be made according to the following formulation:

Ingredient	Percent By Weight
Gum Base	25
Sorbitol Powder	47.125
70% Sorbitol Solution	12
Mannitol Powder	8
Glycerine	6
Color	0.025
Shellac-encapsulated Citric Acid	0.8
Flavor	0.8
Shellac-encapsulated Aspartame	0.25

EXAMPLE IV

A chewing gum containing shellac-encapsulated aspirin, a shellac-encapsulated dried flavor and shellac-encapsulated aspartame can be made according to the

following formation:

Ingredient	Percent By Weight
Gum Base	27.00
Sorbitol Powder	28.725
70% Sorbitol Solution	12.00
Mannitol Powder	8.00
Glycerol	6.00
Color	0.025
Shellac-encapsulated Aspirin	15.00
Shellac-encapsulated Flavor	3.00
Shellac-encapsulated Aspartame	0.25

In all of the foregoing examples, the shellac is present in an amount equal to 25.0% by weight of each encapsulated active ingredient to provide an impermeable, hydrophobic coating.

CLAIMS

1. A chewing gum composition comprising gum base, characterized by a food-grade shellac encapsulant for one or more active ingredients of the group consisting of a sweetener, a flavoring agent, a food-grade acid, a pharmaceutical agent and a breath-freshening agent.

2. The chewing gum composition of claim 1, characterized in that the shellac encapsulant is present in an amount of about 25.0% by weight of the active ingredient.

3. The chewing gum composition of claim 1, characterized in that the active ingredient is encapsulated by a fluidized bed coating method.

4. The chewing gum composition of claim 1, characterized in that the active ingredient is encapsulated by a roller bed coating method.

5. The chewing gum composition of claim 1, characterized in that the active ingredient is a sweetener.

6. The chewing gum composition of claim 5, characterized in that the sweetener is a dipeptide sweetener.

7. The chewing gum composition of claim 6, characterized in that the dipeptide sweetener is aspartame.

8. The chewing gum composition of claim 7, characterized in that the aspartame is present in an amount ranging from about 0.025% to about 2.0% by weight of the gum composition and the encapsulating agent is present in an amount ranging from about 5.0% to about 90.0% by weight of the aspartame.

9. The chewing gum composition of claim 8, characterized in that the shellac encapsulant is present in an amount of about 25.0% by weight of the aspartame.

10. The chewing gum composition of claim 1, characterized in that the active ingredient is a flavoring agent.

11. The chewing gum composition of claim 10, characterized in that the flavoring agent is co-dried on a powdered carrier.

12. The chewing gum composition of claim 1, characterized in that the active ingredient is a food-grade acid.

13. The chewing gum composition of claim 1, characterized in that the active ingredient is a pharmaceutical agent.

14. The chewing gum composition of claim 1, characterized in that the active ingredient is a breath-freshening agent.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/00108

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to [3] tional Patent Classification (IPC) or to both National Classification and IPC

INT. CL.[3] A23G 3/30; A23L 1/236; A23L 1/226

US CL. 426/3,4,5,6,96,302,650,548,804; 424/48,49; 252/318

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	426/3,4,5,6,96,302,548,804,650 252/318 424/48,49

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X	U.S., A. 3,962,463, PUBLISHED 08 JUNE 1976, WITZEL.	1,5-14
	U.S., A, 3,622,352, PUBLISHED 23 NOVEMBER 1971, DAYLOR ET AL.	1-14
,P	U.S., A, 4,384,004, PUBLISHED 17 MAY 1983, CEA ET AL.	1-14
A	U.S., A, 4,259,355, PUBLISHED 31 MARCH 1981, MARMO ET AL.	1-14
A ,P	U.S., A, 4,386,106, PUBLISHED 31 MAY 1983, MERRITT ET AL.	1-14
A	U.S., A, 4,224,345, PUBLISHED 23 SEPTEMBER 1980, TEZUKA ET AL.	1-14
A	U.S., A, 3,985,913, PUBLISHED 12 OCTOBER 1976, JOHNSON ET AL.	1-14
A	U.S., A, 3,576,663, PUBLISHED 27 APRIL 1971.	1-14
A	U.S., A, 3,780,195, PUBLISHED 18 DECEMBER 1973.	1-14

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
23 APRIL 1984	24 APR 1984
International Searching Authority [1]	Signature of Authorized Officer [20]
ISA/US	Jeanette M. Hunter JEANETTE M. HUNTER

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers....., because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

Claim 1 is generic to plurality of disclosed patentably distinct species:
I. Sweetener, flavoring, acid classified in class 426 sub class 3. II. Pharmaceutical, breath freshner classified in class 424 sub class 48.

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.